

EXHIBIT C

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION**

The United States of America and the States of)	
North Carolina, California, Colorado, Delaware,)	
Florida, Georgia, Illinois, Indiana, Iowa, Louisiana,)	
Michigan, Minnesota, New Jersey, New York,)	
Tennessee, Texas, Virginia, and Wisconsin, ex rel.)	C/A No.: 9:14-cv-0230-RMG
Scarlett Lutz, Kayla Webster, Dr. Michael Mayes,)	(Consolidated with 9:11-cv-1593-RMG
and Chris Reidel,)	and 9:15-cv-2485-RMG)
)	
Plaintiffs,)	
)	
v.)	<u>DEFENDANTS BLUEWAVE, DENT,</u>
)	<u>AND JOHNSON'S REQUESTS</u>
Berkeley Heartlab, Inc., BlueWave Healthcare)	<u>FOR JURY INSTRUCTIONS</u>
Consultants, Inc., Latonya Mallory, Floyd Calhoun)	
Dent, III, and Robert Bradford Johnson,)	
)	
Defendants.)	

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 1¹

The fact that the United States Government is the plaintiff, or that defendant BlueWave is a corporation, or that there are individual relators or individual defendants, should not affect your decision. All parties to this litigation are equal before the law, and each should be given the same fair treatment by you.

AUTHORITY: United States Constitution.

GOVERNMENT'S OBJECTION:

¹ Defendants BlueWave Healthcare Consultants, Inc., Calhoun Dent and Bradford Johnson, pursuant to FRCP 51(a), hereby request that the Court give the attached instructions to the jury. These proposed instructions are in addition to the Standard General Civil Jury Instructions as posted on the Court's website and/or Judge Gergel's Special Instructions. Defendants reserve the right to request additional charges as permitted by the Rules. Defendants may also request that certain charges be given at the opening of trial.

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 2

The Government claims that Defendants BlueWave, Dent and Johnson are liable to pay damages for causing the submission of false claims to the Medicare programs in violation of the False Claims Act. The Defendants deny the Government's claims. All of the Government's claims ultimately rest on its contention that the Defendants violated the Anti-Kickback Statute. Therefore, I will explain the provisions of the Anti-Kickback Statute first. I will explain the False Claims Act later. If you find that the Anti-Kickback Statute does not apply or has not been violated, then you must rule in the Defendants' favor. If you find that the Defendants violated the Anti-Kickback Statute, then you still must determine if the Defendants violated the False Claims Act.

AUTHORITY:

Government's Complaint (ECF # 75); Defendants' Amended Answer to Government's Complaint in Intervention (ECF # 267).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 3

The Medicare program is a federal health care insurance program that pays health care providers such as laboratories for health care services that they provide to people over 65 and certain other people who are eligible for Medicare benefits. The Centers for Medicare and Medicaid Services (“CMS”) is the federal agency that is responsible for the administration of Medicare. Under the Medicare program, CMS makes payments retrospectively (after the services are furnished) to health care entities for services provided to or for Medicare beneficiaries.

AUTHORITY:

Government’s Complaint (ECF # 75), Paragraphs 47-63. U.S. ex rel. Drakeford v. Tuomey, 675 F.3d 394, 397 n. 5 (4th Cir. 2012).

GOVERNMENT’S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 4

The TRICARE program is a federal health care insurance program that pays health care providers such as laboratories for health care services that they provide to people who are eligible for TRICARE benefits, which includes active and retired members of the Uniformed Services and their dependents. The Defense Health Agency (“DHA”) is the federal agency that is responsible for the administration of TRICARE. Under the TRICARE program, DHA makes payments retrospectively (after the services are furnished) to health care entities for services provided to or for TRICARE beneficiaries.

AUTHORITY:

Government’s Complaint in Intervention, Paragraphs 64-68.

GOVERNMENT’S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 5

The Anti-kickback Statute (“AKS”) is a criminal statute. In order for the Government to prevail in this case, you must first find that the Defendants violated the Anti-kickback Statute, which provides as follows:

(1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony....

(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony....

AUTHORITY:

Government’s Complaint in Intervention, Paragraphs 32; 42 U.S.C. § 1320a-7b(b)

GOVERNMENT’S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 6

The elements which constitute a violation of the Anti-kickback Statute (“AKS”) are as follows: The defendant acts (1) knowingly and willfully, (2) offers, pays, solicits or receives any remuneration, directly or indirectly, (3) to induce a person to refer individuals to the subject laboratories for the furnishing of medical services, or to induce a person to furnish, arrange or recommend the ordering or purchasing of any services from the subject laboratories, (4) which are paid for by Medicare or TRICARE.

AUTHORITY:

United States ex rel. Mastej v. Health Mgmt. Assocs., Inc., 591 F. App'x 693, 705 (11th Cir. 2014); 42 U.S.C. § 1320a-7b(b).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 7

In order to violate the Anti-kickback Statute (“AKS”), a person must act both knowingly and willfully, that is, a person must act with “criminal intent.” The term “knowingly” “requires proof of knowledge of the facts that constitute the offense.” The term “knowingly” means that an act was done voluntarily and intentionally and not because of a mistake or by accident. The term “willfully” means that the defendant knew “that his conduct was unlawful,” knew he was acting “with a bad purpose,” or knew he was acting “with evil intent without justifiable excuse.” The term “willfully” means that the act was committed voluntarily and purposely, with the intent to do something the law forbids. While the party must have acted with the intent to do something the law forbids before you can find that the party acted willfully, since January 1, 2011, that person need not have actual knowledge of the Anti-Kickback Statute or the specific intent to commit a violation of the Anti-Kickback Statute. Prior to January 1, 2011, a person did need to have actual knowledge of the Anti-Kickback Statute or the specific intent to commit a violation of the Anti-Kickback Statute.

AUTHORITY:

Ratzlaf v. United States, 510 U.S. 135, 137 (1994); Bryan v. United States, 524 U.S. 184, 192-193 (1998); Dixon v. United States, 548 U.S. 1 (2006); United States ex rel. Gonzalez v. Fresenius Medical Care N.A., 748 F.Supp.2d 95, 113 (W.D.Tex. 2010); United States ex rel. Jamison v. McKesson Corp., 900 F.Supp.2d 683 n. 7 (N.D.Miss. 2012); United States ex rel. Sharp v. Consolidated Med. Transp., Inc., No. 96-6502, 2001 WL 1035720, at *10 (N.D. Ill. Sept. 4, 2001); 42 U.S.C. § 1320a-7b(b); 42 U.S.C. § 1320a-7b(g); United States v. TEVA Pharmaceuticals USA, Inc., 2016 WL 750720, at *16 (S.D.N.Y. 2016) (2010 amendment to the Anti-Kickback Statute became effective on January 1, 2011); Hanlester Network v. Shalala, 51 F.3d 1390, 1398 (9th Cir. 1995) (specific intent of AKS law violation required); United States v. McClatchey, 217 F.3d 823, 829 (10th Cir. 2000); United States v. Starks, 157 F.3d 833, 837-38 (11th Cir. 1998).

GOVERNMENT’S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 8

In order to violate the Anti-kickback Statute (“AKS”), “the reason for” or the “primary purpose” or “material purpose” of the remuneration paid must be for the inducement of referrals.

AUTHORITY:

United States v. Bay State Ambulance and Hosp. Rental Serv., Inc., 874 F.2d 20, 33 (1st Cir. 1989) (“The key to a Medicare Fraud case is the reason for the payment—was the purpose of the payments primarily for inducement.”); United States ex rel. v. Villafane v. Solinger, 543 F.Supp.2d 678, 697 (W.D.Ky. 2008) (declining to adopt one-purpose test); United States v. Shaw, 106 F.Supp.2d 103, 121 (D.Mass. 2000) (“the issue for a jury to decide ... is whether the reason for offering or accepting the discount or other reduction in price was to induce referrals”) (court “upheld a jury instruction that read: It is not a defense that there might have been other reasons for the solicitation of a remuneration by the defendants, if you find that one of the material purpose for the solicitation was to obtain money for the referral of services.”); 42 U.S.C. § 1320a-7b(b).

GOVERNMENT’S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 9

As used in the Anti-Kickback Statute, the term “remuneration” means the transfer of anything of value from one person or entity to another person or entity. Remuneration can be direct or indirect. The term "remuneration" under the Anti-Kickback Statute includes transfers of items or services for free or for other than fair market value.

“To induce,” under the Anti-Kickback Statute, means to attempt to gain influence over the reason or judgment of a person improperly or corruptly. A party must prove that remuneration was paid improperly or corruptly or explicitly as a quid pro quo in return for a decision.

It is not unlawful to hope or expect or believe that referrals may ensue from remuneration that was designed wholly for other purposes. Likewise, mere oral encouragement to refer patients or the mere creation of an attractive place where patients can be referred does not violate the law. There must be an offer or payment of remuneration to induce, as I have just defined it.

AUTHORITY:

Ameritox, Ltd. v. Millennium Laboratories, Inc., No. 8:11-cv-775-T-24-TBM, ECF # 622 at 17 (M.D.Fl. June 16, 2014) (jury instructions) (attached); 42 U.S.C. § 1320a-7b(b); Hanlester Network v. Shalala, 51 F.3d 1390, 1398 (9th Cir. 1995) (induce means to have “an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business.”)

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 10

In order to find in favor of the Government, you must find that the evidence clearly and convincingly establishes a violation of the False Claims Act. At all times it is the Government's burden of proof to establish its False Claims Act claims through clear and convincing evidence. Clear and convincing evidence means evidence which produces in the mind of the trier of fact a firm belief of conviction as to the truth of the allegations sought to be established, evidence so clear, direct and weighty and convincing as to enable the factfinder to come to a clear conviction, without hesitancy, of the truth of the precise facts in issue.

AUTHORITY:

Due Process Clause of the 5th and 14th Amendments; LaSalle, Frank (1995), "The Civil False Claims Act: The Need for a Heightened Burden of Proof as a Prerequisite for Forfeiture," Akron Law Review, Vol.28: Iss. 3, Article 9;² Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261, 286 n. 11 (1990).

GOVERNMENT'S OBJECTION:

² (<http://ideaexchange.uakron.edu/akronlawreview/vol28/iss3/9>)

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 11

In order to find in favor of the Government, you must find that the evidence establishes a violation of the Anti-Kickback Statute beyond a reasonable doubt. At all times it is the Government's burden of proof to establish violations of the Anti-Kickback Statute with evidence that proves the violation beyond a reasonable doubt. The Government must prove each element of an Anti-Kickback Statute violation to each and every one of you beyond a reasonable doubt. If the Government fails to prove an element of an Anti-Kickback Statute violation beyond a reasonable doubt, then you must find for the Defendants. While the Government's burden of proof is a strict and heavy burden, it is not necessary that it be proved beyond all possible doubt. It is only required that the Government's proof exclude any reasonable doubt concerning that element. The Defendants never have the burden of disproving the existence of anything which the Government must prove beyond a reasonable doubt. The burden is wholly upon the Government. The law does not require the Defendants to produce any evidence with respect to any alleged Anti-Kickback violations. A "reasonable doubt" is a doubt based upon reason and common sense after careful and impartial consideration of all the evidence in the case. Proof beyond a reasonable doubt, therefore, is proof of such a convincing character that you would be willing to rely and act upon it without hesitation in the most important of your own affairs.

AUTHORITY: Eric Wm. Ruschky, Pattern Jury Instructions for Federal Criminal Cases, District of South Carolina § II.B (Burden of Proof); U.S. v. McClatchey, 217 F.3d 823, 829 (10th Cir. 2000) (AKS burden of proof is beyond a reasonable doubt); In re Winship, 397 U.S. 358, 364 (1970) (required beyond a reasonable doubt in a non-criminal proceeding); U.S. ex rel. Jamison v. McKesson Corp., 900 F.Supp.2d 683 n. 7 (N.D. Miss. 2012) ("the Court acknowledges that if this case were a closer call, the proper course would likely be to use criminal intent to prove a civil AKS violations."); U.S. ex rel. Gonzalez v. Fresenius Medical Care N.A., 748 F.Supp.2d 95, 113 (W.D.Tex. 2010); (failure to show AKS "criminal intent to induce referrals"); U.S. ex rel. Sharp v. Consolidated Med. Transp., Inc., No. 96-6502, 2001 WL 1035720, at *10 (N.D. Ill. Sept. 4, 2001) (FCA claim under the AKS "requires criminal intent"); U.S. v. Laughlin, 26 F.3d 1523, 1527 (10th Cir. 1994).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 12

Since January 1, 2011, “a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of establishing a violation of the False Claims Act. That is, if a claim is proximately caused by or results from an Anti-Kickback Statute violation, the claim is false for purposes of the False Claims Act. However, the Government must still prove that a Defendant willfully and knowingly submitted any such claim knowing that it was false. Prior to January 1, 2011, a claim that included items or services resulting from a violation of the Anti-Kickback Statute was not necessarily nor statutorily false.

AUTHORITY:

42 U.S.C. § 1320a-7b(g) (“In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31.”); United States v. TEVA Pharmaceuticals USA, Inc., 2016 WL 750720, at *16 (S.D.N.Y. 2016) (“A 2010 amendment to the Anti-Kickback Statute, which became effective on January 1, 2011, states that a claim for services that violates the Anti-Kickback Statute also violates the FCA.”); United States ex rel. Hutcheson v. Blackstone Med., Inc., No. 06-11771-WGY, 2010 WL 938361 (D. Mass. Mar. 12, 2010), reversed, 647 F.3d 377 (1st Cir. 2011); United States ex rel. Thomas v. Bailey, 2008 WL 4853630 (E.D. Ark. 2008).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 13

There are a number of statutory and regulatory safe harbors which protect certain arrangements from being in violation of the Anti-Kickback Statute. “To receive protection, a business arrangement must fit squarely within a safe harbor; substantial compliance is not enough, although compliance is voluntary and failure to comply is not a per se violation of the statute.” That is, just because the Defendants’ conduct or arrangements do not fit within a safe harbor does not mean that their conduct or arrangements violate the Anti-Kickback Statute. “Liability under the Anti-Kickback Statute ultimately turns on the intent of the parties and will depend on the facts and circumstances present in each case.”

AUTHORITY:

42 U.S.C. § 1320a-7b(b)(3)(A)–(J); 42 C.F.R. § 1001.952 ; United States ex rel. Westmoreland v. Amgen, Inc., 812 F.Supp.2d 39, 47 (D.Mass. 2011); United States ex rel. Bartlett v. Ashcroft, 39 F.Supp.3d 656, 676 (W.D.Pa. 2014)

GOVERNMENT’S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 14

In Count 1 of the Government's Complaint, the Government alleges what is known as a presentment action under the False Claims Act. The False Claims Act provides that "any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" is liable to the United States for damages.

Thus, to prove a violation of a presentment action under the False Claims Act, the Government must prove the following elements: that the Defendants (1) knowingly presented or caused to be presented, (2) a false claim, (3) to the United States government, (4) knowing its falsity, (5) which was material, and (6) was seeking payment from the federal treasury.

The Government bears the burden of proving each False Claims Act element for each false claim.

AUTHORITY:

United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 376 (4th Cir. 2008); United States ex rel. Hutcheson v. Blackstone Med., Inc., No. 06-11771-WGY, 2010 WL 938361 (D. Mass. Mar. 12, 2010), reversed on other grounds, 647 F.3d 377 (1st Cir. 2011); 31 U.S.C. § 3729(a)(1)(A); Complaint at Count 1; United States ex rel. Sanders v. North American Bus Industries, Inc., 546 F.3d 288 (4th Cir. 2008).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 15

In Count 2 of the Government's Complaint, the Government alleges what is known as a false statement action under the False Claims Act. The False Claims Act provides that "any person who knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" is liable to the United States for damages.

Thus, to prove a false statement action violation under the False Claims Act, the Government must prove the following elements: that the Defendants (1) knowingly made or used (or caused to be made or used) a statement or record, (2) the statement or record was false, (3) the Defendants knew the statement or record to be false, and (4) the statement or record was material to a false claim. The Government must prove "(1) the defendant [knowingly] made a false record or statement for the purpose of getting a false claim paid or approved by the government; and (2) the defendant's false record or statement caused the government to actually pay a false claim." Only false statements or records which have the purpose and effect of causing the government to pay out money where it is not otherwise due are actionable under the False Claims Act. The payment must be the direct and proximate result of the false statement or record.

AUTHORITY: 31 U.S.C. § 3729(a)(1)(B); United States ex rel. Phalp v. Lincare Holdings, Inc., 857 F.3d 1148, 1154 (11th Cir. 2017); United States ex rel. Gacek v. Premier Medical Management, Inc., 2017 WL 2838179, at *7 (S.D.Ala. 2017); United States ex rel. Hood v. Satory Global, Inc., 946 F.Supp.2d 69, 85 (D.D.C. 2013); John T. Boese, Civil False Claims and Qui Tam Actions § 2.05 (3d ed.); United States ex rel. Longhi v. U.S., 575 F.3d 458, 473 (5th Cir. 2009); United States v. Miller, 645 F.2d 473, 475-76 (5th Cir. 1981); Complaint at Count 2.

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 16

The False Claims Act provides that any person who knowingly conspires to violate a provision of the False Claims Act is liable to the United States for damages. Here, the Government alleges in Count 3 that the Defendants knowingly conspired to file false and fraudulent claims in violation of the False Claims Act.

To prove a civil conspiracy violation under the False Claims Act, the Government must prove the following elements: (1) that “an agreement existed [between the Defendants] to have false or fraudulent claims allowed or paid” to the government, (2) that each alleged member of the conspiracy knowingly “joined that agreement,” and (3) that “one or more conspirators knowingly committed one or more overt acts in furtherance of the object of the conspiracy.”

The Government must demonstrate a meeting of the minds on the object or course of action. To establish a meeting of the minds, it is not sufficient for the Government to prove that the alleged conspirators intended to engage in the conduct that resulted in the injury. Instead, the alleged conspirators must be aware of the harm or wrongful conduct to be committed at the inception of the combination or agreement, and must commit an overt act in furtherance thereof.

An entity or corporation “cannot conspire with its employees, and its employees, when acting within the scope of their employment, cannot conspire among themselves.” No conspiracy can exist without “some underlying tortious or fraudulent act.” Thus, in the context of the False Claims Act, this means that there can be no liability for conspiracy where there is no underlying violation of the False Claims Act.

AUTHORITY: 31 U.S.C. § 3729(a)(1)(C); United States ex rel. Miller v. Bill Harbert Int'l Constr., Inc., 608 F.3d 871, 899 (D.C.Cir. 2010); Pencheng Si v. Laogai Research Foundation, 71 F.Supp.3d 73, 89 (D.D.C., 2014); Halberstam v. Welch, 705 F.2d 472, 477 (D.C.Cir. 1983); U.S. ex rel. Reagan v. East Texas Med. Ctr. Reg. Healthcare Sys., 274 F. Supp. 2d 824, 857 (S.D. Tex. 2003); Complaint at Count 3.

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 17

Under the False Claims Act, (1) the terms “knowing” and “knowingly” --

(A) mean that a person, with respect to information--

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud.

Reckless disregard is more than gross negligence. Innocent mistakes, mere negligence, or even gross negligence (without more) are not actionable under the False Claims Act. Flawed reasoning and disputed legal issues arising from vague provisions or regulations cannot support liability under the False Claims Act. The failure to comply with administrative regulations is not standing alone evidence of reckless disregard.

AUTHORITY:

31 U.S.C. § 3729(b)(1); United States ex. rel. Longhi v. Lithium Power Tech., 513 F. Supp. 2d 866, 875-76 & n.9 (S.D. Tex. 2007); Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson, 545 U.S. 409, 418 (2005).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 18

Under the False Claims Act, (2) the term “claim”--

(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that--

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government--

(I) provides or has provided any portion of the money or property requested or demanded; or

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

AUTHORITY:

31 U.S.C. § 3729(b)(2).

GOVERNMENT’S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 19

A claim for payment to the Government has to be materially false in order to violate the False Claims Act. The term “material” means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” “A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance.” The materiality standard is demanding.

“When evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.” If you find that the Government knew about the underlying facts about the Defendants’ alleged fraudulent conduct, but continued to pay claims submitted, you must find for the Defendants.

AUTHORITY: Universal Health Services, Inc. v. United States, 136 S.Ct. 1989, 2003–04 (2016); 31 U.S.C. § 3729(b)(4); City of Chicago v. Purdue Pharma, LP, 211 F.Supp.3d 1058 (N.D. Ill. 2016) (because claims were paid after lawsuit filed they were not material).

GOVERNMENT’S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 20

“Good faith” is a defense to allegations that the Defendants violated the Anti-Kickback Statute or the False Claims Act. While the term “good faith” has no precise definition, it encompasses, among other things, a belief or opinion honestly held or an absence of malice or ill will. A person who acts, or causes another person to act, on a belief or an opinion honestly held is not punishable under the Anti-Kickback Statute merely because that belief or opinion turns out to be inaccurate, incorrect, or wrong. In determining whether a party acted willfully, or whether it acted in good faith, you must consider all of the evidence received in the case bearing on that party’s state of mind. During this case, both parties offered evidence that that they consulted with outside experts regarding certain challenged business practices. You may only consider this evidence to determine whether each party acted in good faith. You may not consider this evidence as proof that any challenged business practice is legal. The defense of good faith is not an affirmative defense, that is, the Defendants do not have the burden of proof to prove good faith. The burden is on the Government to prove Defendants lacked good faith. Whether the defendants have violated the Anti-Kickback Statute or the False Claims Act is for you to decide.

AUTHORITY: Ameritox, Ltd. v. Millennium Laboratories, Inc., No. 8:11-cv-775-T-24-TBM, ECF # 622 at 18 (M.D.Fl. June 16, 2014) (jury instructions).

GOVERNMENT’S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 21

Defendants have asserted an affirmative defense of advice of counsel to the Government's allegations that they violated the False Claims Act. An affirmative defense is an argument that, if true, will completely defeat the Government's allegations under the False Claims Act. The Defendants have the burden of proving their affirmative defense by a preponderance of the evidence.

AUTHORITY:

United States ex rel. Drakeford v. Tuomey Healthcare System, Inc., No. 3:05-cv-02858-MBS, ECF # 810 at 13 (jury instructions) (attached).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 22

In order for Defendants to prevail on their advice of counsel affirmative defense, they must prove the following:

1. The advice was sought in good faith;
2. The client provided full and accurate information to the attorney;
3. The advice could be reasonably relied upon; and
4. The client faithfully followed the attorney's advice.

Defendants cannot rely on the advice of counsel defense if they did not disclose full and accurate information, including all material facts, to their attorneys. If you find that Defendants did not disclose full and accurate information to their attorneys, including all material facts, then you should find that Defendants cannot prevail on their affirmative defense of advice of counsel. If you find, however, that Defendants met their burden of proof as to the affirmative defense, then you must return a verdict in favor of the Defendants as to the False Claims Act.

The advice of counsel defense is a complete defense to the Government's false claims suit even if that advice turned out to be wrong.

AUTHORITY:

United States ex rel. Drakeford v. Tuomey Healthcare System, Inc., No. 3:05-cv-02858-MBS, ECF # 810 at 14 (jury instructions) (attached); United States ex rel. Drakeford v. Tuomey, 792 F.3d 364, 381 (4th Cir. 2015); United States v. Painter, 314 F.2d 939, 943 (4th Cir. 1963); U.S. v. Newport News Shipbuilding Co., 276 F.Supp.2d 539, 565 (E.D.Va. 2003).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 23

The False Claims Act requires a Defendant to act knowingly and the Anti-Kickback Statute requires a Defendant to act knowingly and willfully. However, neither the False Claims Act nor the Anti-Kickback Statute requires that a Defendant have specific intent to violate the respective statutes. That is, a Defendant does not have to know that his or her conduct specifically violates the False Claims Act nor the Anti-Kickback Statute.

AUTHORITY:

31 U.S.C. § 3729(b)(1)(B); 42 U.S.C. § 1320a-7b(h)

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 24

In the context of the Anti-Kickback Statute, “Fair Market Value” is used as the gauge of value when assessing the remuneration element of the offense. Fair Market Value is the “price that a seller is willing to accept and a buyer is willing to pay on the open market and in an arms'-length transaction” when “neither is under compulsion to buy or sell.” In order to comply with the Anti-Kickback Statute, remuneration must be paid at fair market value.

AUTHORITY:

Jamison v. McKesson Corp., 900 F.Supp.2d 683, 699 (N.D.Miss. 2012); Klaczak v.

Consolidated Medical Transport, 458 F.Supp.2d 622 (N.D. Ill. 2006) (defining fair market value; to comply with the Anti-Kickback Statute, the hospital must simply pay fair market value for the practice's assets)

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 25

“Claims for services rendered in violation of a statute [or regulation] do not necessarily constitute false or fraudulent claims under the [False Claims Act].” The Government must prove that the Defendants knowingly lied about compliance with statutes or regulations.

AUTHORITY:

Gonzalez v. Fresenius Med. Care N. Am., 689 F.3d 470, 475 (5th Cir. 2012); United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1997); United States ex rel. Farmer v. City of Houston, 523 F.3d 333, 340 & n.12 (5th Cir. 2008).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 26

Claims submitted based on differences of interpretation growing out of disputed legal questions, such as differing interpretations of the Anti-Kickback Statute, are not considered “false” under the False Claims Act. Therefore, if you determine that the BlueWave Defendants believed the Process and Handling Fee contracts with physicians did not violate the law, you must find in favor of the BlueWave Defendants on the claims related to the Process and Handling Fee agreements.

AUTHORITY:

U.S. ex rel. Wilson v. Kellogg, Brown & Root, Inc., 525 F.3d 370, 377 (4th Cir. 2008).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 27

Claims submitted to Medicare or TRICARE would not be considered to be knowingly submitted if based on a reasonable interpretation of ambiguous regulations that the claims did not violate the Anti-Kickback Statute, even if the interpretation is flawed. Therefore, if you find that Singulex or Health Diagnostic Laboratory (“HDL”) submitted Medicare or TRICARE claims for services referred by the physicians based on a reasonable interpretation of ambiguous regulations, even if the interpretation was flawed, you must rule in favor of the Defendants.

AUTHORITY:

United States v. Race, 632 F.2d 1114 (4th Cir. 1980); U.S. ex rel. Lockyer v. Hawaii Pacific Health Group, 343 Fed. Appx. 279, 281 (9th Cir. 2009); U.S. ex rel. Augustine v. Century Health Services, Inc., 136 F.Supp. 2d 876, 890 (M.D. Tenn. 2000), aff'd, 289 F.3d 409 (6th Cir. 2002).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 28

The Government has alleged that one or more laboratory tests were not medically necessary nor medically reasonable which resulted in Health Diagnostic Laboratory (HDL) and Singulex having the requisite intent or scienter to knowingly file false claims to Medicare and TRICARE. Medicare and TRICARE require that claims only be submitted for medically necessary and reasonable tests and procedures. However, when there is a mere difference of opinion as to whether a laboratory test is medically necessary and reasonable for a particular patient, there can be no knowing False Claims Act scienter or intent. “Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false.” The Government cannot prove a violation of the False Claims Act simply by calling into question a health care provider’s judgment regarding a specific course of treatment for a patient.

AUTHORITY:

United States v. AseraCare, Inc., 153 F. Supp. 3d 1372 (N.D. Ala. 2015); 42 U.S.C. § 1395y; United States ex rel. Bailey v. Ector County Hosp., 386 F. Supp. 2d 759, 766 (W.D. Tex. 2004).

GOVERNMENT’S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 29

It is the Government's burden to establish that the Defendants' interpretation of the Anti-Kickback Statute or related regulations was unreasonable.

AUTHORITY:

United States ex rel. Augustine v. Century Health Services, Inc., 136 F.Supp. 2d 876, 890 (M.D. Tenn. 2000), aff'd, 289 F.3d 409 (6th Cir. 2002).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 30

The fact that any of the Defendants' attorneys may have advised them to act more cautiously than the law requires or warned them that their conduct had the potential to embroil them in controversy with the Government does not mean that the Defendants were being advised that their conduct was illegal.

AUTHORITY:

U.S. v. DeFries, 129 F.3d 1293, 1309 (D.C. Cir. 1997).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 31

The Defendants may still be found to be relying on its attorneys' advice in good faith even though they may have disregarded some of the attorneys' suggestions.

AUTHORITY:

U.S. v. DeFries, 129 F.3d 1293, 1309 (D.C. Cir. 1997).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 32

The Medicare statute prohibits the federal government from interfering with how doctors and laboratories provide medical services or practice medicine and from exercising any supervision or control over the compensation of any employee or officer of a health care provider.

AUTHORITY:

42 U.S.C. § 1395.

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 33

The Office of Inspector General (“OIG”) also has an advisory opinion process related to questions that arise under the Anti-Kickback statute. However, the OIG does not address through the advisory opinion process whether the fair market value was, or will be, paid or received for any goods, services, or property. The OIG cannot opine on the intent of the parties to a particular arrangement. OIG advisory opinions are not admissible in evidence.

AUTHORITY:

42 U.S.C. § 1320a-7d(b)(3)(A); 42 C.F.R. § 1008.55.

GOVERNMENT’S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 34

The fact that the Defendants did not seek advisory opinions from the Government is not relevant to determining whether the arrangements in question violated the Anti-Kickback Statute or the False Claims Act.

AUTHORITY:

42 U.S.C. § 1320a-7d(b)(4)(B); 42 CFR § 411.388.

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 35

During the trial, you may hear certain audio recordings. You may also be shown transcripts of those recordings that were prepared by the Government. Please understand that the recording itself and not the transcript is the evidence of what was said. Differences in meaning may be caused by such factors as the inflection in a speaker's voice or in inaccuracies in the transcript, so you should rely on what you hear rather than what you read if you think there is a difference.

AUTHORITY:

U.S. v. Collazo, 732 F.2d 1200 (4th Cir. 1984).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 36³

You have heard some non-party witnesses assert the 5th Amendment Constitutional right against self-incrimination in response to questions from attorneys. You are to ignore the impact of these witnesses' refusal to testify in response to questions from attorneys, and you may not draw any adverse inference against the parties to this litigation due to these witnesses' refusal to answer questions. In particular, you may not draw any adverse inference against any of the Defendants due to any non-party witness' assertion of his or her 5th Amendment right to not testify.

AUTHORITY:

Auto-Owners Ins. Co. v. Newsome, No. 4:12-cv-00447, 2013 WL 5797729 at n. 4 (D.S.C. Oct. 25, 2013).

GOVERNMENT'S OBJECTION:

³ This Requested Jury Instruction assumes the Court allows non-party witnesses, who have previously asserted the 5th Amendment and refused to answer questions during depositions, to testify at trial in this case. If the Court excludes such anticipated witnesses from testifying, this Requested Jury Instruction shall be withdrawn.

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 37

The Anti-Kickback Statute contains safe harbors which, if met, exempt those arrangement from liability under the Anti-Kickback Statute. One such safe harbor is the Personal Services and Management Contracts Safe Harbor. It provides as follows:

- “Remuneration” does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met:
- (1) The agency agreement is set out in writing and signed by the parties.
 - (2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
 - (3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
 - (4) The term of the agreement is for not less than one year.
 - (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
 - (6) The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.
 - (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

As used herein, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

AUTHORITY: 42 C.F.R. § 1001.952(d).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 38

Even if you were to find that the Defendants knowingly caused the submission of claims in violation of the Anti-Kickback Statute, the Government must show not only that the laboratories' Medicare and TRICARE claims caused the Government to make payments that it would have otherwise withheld, but also that the performance the Government received was worth less than what it believed it had purchased. "In other words, the Government cannot claim a loss when it reimbursed a Medicare [or TRICARE] provider for services that were actually rendered unless the payment exceeds the value of the services."

AUTHORITY:

U.S. ex rel. Davis v. Dist. of Columbia, 679 F.3d 832, 839 (D.C. Cir. 2012); U.S. ex rel. Harrison v. Westinghouse Savannah River Co., 352 F.3d 908, 923 (4th Cir. 2003); United States v. Razalan, 725 F.Supp.2d (E.D.Mich. 2010) (government cannot claim a loss when a defendant was reimbursed for legitimate services even though tainted by kickbacks); United States v. Vaghela, 169 F.3d 729, 736 (11th Cir. 1999).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 39

In order to recover the full value of the claims made by HDL and Singulex to Medicare and TRICARE, the Government must prove that it received no value from the laboratories' test services provided to Medicare and TRICARE beneficiaries by HDL and Singulex.

AUTHORITY:

United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1279 (D.C. Cir. 2010); United States ex rel. Harrison v. Westinghouse Savannah River Co., 352 F.3d 908, 923 (4th Cir. 2003); Mikes v. Strauss, 274 F.3d 687, 701 (2d Cir. 2001); United States ex rel. Wall v. Circle C. Construction, No. 14-6150, 2016 WL 423750 (6th Cir. Feb. 4, 2016).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 40

To prove a violation of the False Claims Act, with respect to the BlueWave Defendants, the Government is required to prove that the BlueWave Defendants' actions and conduct were the proximate cause of the submission of false claims to Medicare and TRICARE by HDL and Singulex. That is, the Government must prove that the submission of false claims to Medicare and TRICARE by HDL and Singulex was a necessary, foreseeable and obvious consequence of the BlueWave Defendants' actions and conduct, and that their actions and conduct were a substantial factor in the filing of such false claims.

AUTHORITY:

United States ex rel. DeCesare v. Americare In Home Nursing, 757 F.Supp.2d 573, 589 (E.D. Va. 2010); ECF # 268 at 10.

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 41

If you find that the Government has established all of the elements of its claims under the False Claims Act, you then must determine the amount of damages, if any, which the United States sustained as a direct result of the violation.

The measure of damages resulting from the Defendants' violation of the False Claims Act, if any, shall be the difference between what the United States actually paid on the false claim and what it would have paid had it known the false nature of the material facts represented. Stated another way, the measure of the United States' damages under the False Claims Act is the amount paid out by reason of the false claim, over and above what it would have paid if the claim had not been false.

AUTHORITY:

31 U.S.C. § 3729(a); United States ex rel. Longhi v. U.S., 575 F.3d 458, 468 (5th Cir. 2009); United States v. Aerodex, Inc., 469 F.2d 1003, 1011 (5th Cir. 1972); John T. Boese, Civil False Claims and Qui Tam Actions Appendix F (3d ed.).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 42

The Government has the burden of proving each element on its counts on a claim-by-claim basis. In other words, the Government must prove by clear and convincing evidence which claims submitted by HDL and Singulex, or caused to be submitted by the Defendants, satisfy all of the required elements under the False Claims Act. You are not permitted to speculate that elements found to exist with respect to one claim apply to other claims, unless there is evidence linking the conduct to those other claims.

AUTHORITY:

United States v. Krizek, 7 F. Supp. 2d 56, 58-59 (D.D.C. 1998); Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 545 U.S. 409, 418 (2005); John T. Boese, Civil False Claims and Qui Tam Actions § 5.08[A][2] (3d ed.)

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 43

The False Claims Act attaches liability not to any underlying fraudulent activity or to the Government's wrongful payment, but to the claim for payment.

AUTHORITY:

United States ex rel. Graves v. ITT Educ. Serv., Inc., 284 F. Supp. 2d 487, 495 (S.D. Tex. 2003).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 44

The False Claims Act penalizes a person for his own acts, not the acts of someone else. Mere inaction is not sufficient to constitute a violation of the False Claims Act.

AUTHORITY:

United States v. Bornstein, 423 U.S. 303, 312 (1976); United States ex rel. Piacentile v. Wolk, 1995 WL 20833 at *4 (E.D. Pa. 1995).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 45

The Anti-Kickback Statute is aimed at the inducement factor. This means that to succeed on the three counts against the Defendants, the Government must prove beyond a reasonable doubt that they knowingly and willfully intended to induce Medicare and TRICARE patient referrals by knowingly and willfully offering, providing, or paying the particular improper remuneration at issue.

AUTHORITY: 42 U.S.C. § 1320a-7b(b)(1); Polk County v. Peters, 800 F. Supp. 1451, 1454 (E.D. Tex. 1992); Feldstein v. Nash Cmty. Health Serv., Inc., 51 F. Supp. 2d 673, 681 (E.D.N.C. 1999); United States v. Picciotti, 40 F. Supp. 2d 242, 248 (D.N.J. 1999).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 46

The Defendants assert a defense that all of the Plaintiffs' claims are barred by the doctrine of laches, which is based on the notion that people are not supposed to sleep on their rights. The defense of laches has three elements:

- (1) A delay in asserting a right or claim;
- (2) That the delay was inexcusable; and
- (3) That undue prejudice resulted from the delay.

If you conclude that the Defendants have established these elements, then your verdict must be for the Defendants.

AUTHORITY:

United States v. Ajaegbu, 165 F.3d 24, 1998 WL 870705 at *2 (5th Cir. 1998)

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 47

Under the False Claims Act, the relators are entitled to receive between 15% and 30% of whatever amount you award the United States. This amount is determined by me after your verdict is reached. Accordingly, you may consider the relators' interests in this claim only in determining whether they have testified truthfully about the false claims or statements which were allegedly made to the Government.

AUTHORITY:

31 U.S.C. § 3730(d)(2); U.S. v. U.S. ex rel. Thornton, 207 F.3d 769, 771 (5th Cir. 2000); John T. Boese, Civil False Claims and Qui Tam Actions Appendix F (3d ed.).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 48

In calculating damages under the False Claims Act, if any, you may not consider whether a defendant profited from activity that was subject of a false claim, nor may you consider the amount of any such profit. Rather, you may only award damages in the amount of the actual loss to the United States caused by the false claim, using the measures that I have provided.

AUTHORITY:

United States ex rel. Taylor v. Gabelli, 2005 WL 2978921 at *3-6 (S.D.N.Y. 2005)

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 49

The Government must prove the amount of damages with reasonable certainty. Thus, the Government must prove both that the fact of damages to the United States is certain and that the amount of damages can be reasonably computed. If the Government fails to do so, your verdict must be for the Defendants.

AUTHORITY:

United States ex rel. Ervin v. Hamilton Securities Group, 370 F. Supp. 2d 18, 55

(D.D.C. 2005).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 50

You must not award damages more than once for the same injury. For example, if the Government prevails on two counts and establishes a dollar amount of actual damages suffered by the United States as a direct result of submitting false claims, you must not award any additional actual damages on each count of the separate counts. The United States is only entitled to be made whole once, and may not recover more than it has lost.

AUTHORITY:

2006 Fifth Circuit Civil Jury Instructions 15.14 (Multiple claims).

GOVERNMENT'S OBJECTION:

DEFENDANTS' REQUEST FOR JURY INSTRUCTION NUMBER 51

You should not interpret the fact that I have given instructions about damages as an indication in any way that I believe that the Government should, or should not, win this case.

AUTHORITY:

2006 Fifth Circuit Civil Jury Instructions 2.22

GOVERNMENT'S OBJECTION:

Respectfully submitted,

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